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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,792	11/16/2000	Mary Collins		3965

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	16

DATE MAILED: 08/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary	Application No.	Applicant(s)	
	09/714,792	COLLINS ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,41 and 46-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,41 and 46-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Detailed Office Action

1. Receipt of Applicants' arguments and amendments filed in Paper No.15 on 09 June 2003 is acknowledged. Claim 38-40 and 42-45 have been canceled, claim 18, 41 have been amended and claims 46-85 have been added. Thus claims 18, 41 and 46-85 are pending and under consideration.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed in Paper No.15, 06/09/03:

(I) The objection to the specification.

(II) The objection to claims 18 and 41.

(III) The rejection of claim 18 made under 35 U.S.C. 112, first paragraph.

(IV) The rejection of claim 18 made under 35 U.S.C. 102(b) as being anticipated by Hopp et al (U.S. Patent 5,011,912).

Response to Arguments:

3a. Claim 41 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,248,714. It is acknowledged that Applicants intend to file a terminal disclaimer upon allowance of claim 41 of instant application to overcome this rejection.

3b. Claims 18 and 41stand rejected under 35 U.S.C. 112, second paragraph. The term "specifically" recited in claims 118 and 41 is a relative term which renders the claims indefinite. The term "specifically" is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Appropriate correction is required.

New Rej ctions:

Claim rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 46-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody that binds to an isolated IL-13bc protein, said IL-13bc protein consisting of the amino acid sequence set forth in SEQ ID NO:4; or from amino acids 26 to 341 of SEQ ID NO:4 or from amino acid residue 363 to 380 of SEQ ID NO:4, and a method of treating asthma or allergic conditions by administering said antibody into a mammalian subject suffering from said disease, is not enabling for an antibody that binds to "all" possible IL-13bc proteins or a method of treating all of the recited diseases in a mammalian subject by administering to said subject said antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 46 and 54 are single means claims (M.P.E.P. 2164.08(a)). In In re Hyatt, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983), the Courts have held that: "A single means claim, i.e. where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph." (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because

the specification disclosed at most only those means known to the inventor). Since no material limitations for the antibody that binds to "all" possible human IL-13bc proteins have been recited in claims 46 and 54, the claims encompass every conceivable structure (means) for achieving the stated property (result), a fact situation comparable to Hyatt. The claimed invention encompasses antibodies not envisioned or described in the specification, and neither does the specification disclose how these claimed antibodies can be distinguished from each other. The specification only enables the antibody that binds to the isolated IL-13bc protein, wherein said IL-13bc protein consists of the amino acid sequence set forth in SEQ ID NO:4; or from amino acids 26 to 341 of SEQ ID NO:4 or from amino acid residue 363 to 380 of SEQ ID NO:4, said antibody having specific structure, characteristics and properties. These properties may differ structurally, chemically and physically from other known antibodies.

Claims 50, 52, 58, 60, 66, 68, 74, 76, 82 and 84 are overly broad, because instant specification does not enable a method of treating all of the recited diseases by administering an antibody that binds to IL-13bc. Instant specification discloses that IL-13 is involved in Ig-mediated conditions, including asthma and immune complex diseases such as thyroiditis, Grave's disease, lupus, (page 12, lines 16-30). However, instant specification does not demonstrate that IL-13 is involved in cancer. There are disparate types of cancer caused by various culprits. Therefore, cancer is not one disorder that can be treated by a single agent. Thus the instant specification is non-enabling for a method of treating cancer in a mammalian subject by administering to said subject an antibody that binds to the polypeptide of SEQ ID NO: 4 or fragments

thereof, because there is no disclosure that the claimed antibody would be effective in treating cancer.

Claims 62, 70 and 78 are overly broad for reciting an antibody that binds to a "biologically active fragment" or to a "variant" of IL-13-bc. The instant specification does not outline residues of SEQ ID NO:4 which are considered important for the functional and structural integrity of IL-13bc, so as to design an antibody that bind to said regions. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. The instant specification does not provide a description of a repeatable process of producing an antibody that binds to a biologically active fragment of IL-13bc or a variant of IL-13bc. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues of the disclosed the polypeptide of SEQ ID NO:4, which are required for functional and structural integrity of the protein. It is this additional characterization of the disclosed protein that is required in order to obtain the functional and structural data needed to permit one to produce an antibody which meets both the structural and functional requirements of the instant claims that constitutes undue experimentation. The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation

necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant case, the quantity of experimentation to determine which of the enormous number of nucleic acids that are capable of hybridizing to the nucleic acid of SEQ ID NO:3, would encode a variant of IL-13bc with the desired property, or which fragments of "all" possible IL-13bc proteins retain the desired biological activity as encompassed by the scope of the claims is practically infinite and the guidance provided in the specification very little. Furthermore, the amount of embodiments corresponding to the desirable antibodies, may be innumerable, and the enabled embodiments amount to only the antibody that binds to the isolated IL-13bc protein, said IL-13bc protein consisting of the amino acid sequence set forth in SEQ ID NO:4; or from amino acids 26 to 341 of SEQ ID NO:4 or from amino acid residue 363 to 380 of SEQ ID NO:4.

4b. Claims 62-85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 62 of the instant Application is drawn to an antibody that binds to a fragment of IL-13bc that has biological activity, claim 70 is drawn to an antibody to IL-13bc protein encoded by a nucleic acid which varies from the nucleic acid sequence of SEQ ID NO:3 as a result of the degeneracy of the genetic code, and claim 78 is drawn

to an antibody to IL-13bc variant. However, the specification as filed does not describe the structure of the fragment of claim 62, or the nucleic acid that varies from SEQ ID NO:3 recited in claim 70, or the IL-13bc variant of claim 78. Therefore, conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention.

To satisfy the written description requirement, an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention. Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997); Hyatt v. Boone, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998). Furthermore, In The Reagents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. Adequate written description requires more than a mere statement that it is part of the invention. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In the instant case, Applicant is

claiming antibody that binds to fragments or variants of IL-13bc, however, Applicants do not provide the structure of any of said variants or fragments.

The written description in this case only discloses an antibody that binds to an isolated IL-13bc protein, said IL-13bc protein consisting of the amino acid sequence set forth in SEQ ID NO:4; or from amino acids 26 to 341 of SEQ ID NO:4 or from amino acid residue 363 to 380 of SEQ ID NO:4, and therefore the written description is not commensurate in scope with the claims drawn to an antibody that binds to fragments with biological activity or variants of IL-13bc as recited in claims 62, 70 and 78. Support for fragments with biological activity is provided in the specification on page 7, lines 15-20, wherein it is disclosed that a biologically active fragment is one that has the ability to bind to IL-13. However, instant specification does not disclose which residues of the IL-13bc are needed for the functional and structural integrity of the IL-13bc. Neither does the specification describe the structure of a biologically active fragment of IL-13bc or a variant of IL-13bc.

Therefore only an antibody that binds to an isolated IL-13bc protein, said IL-13bc protein consisting of the amino acid sequence set forth in SEQ ID NO:4; or from amino acids 26 to 341 of SEQ ID NO:4 or from amino acid residue 363 to 380 of SEQ ID NO:4, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. 112, first paragraph. As a result, it does not appear that the inventors were in possession to an antibody that binds to a fragment of IL-13bc that has biological activity, or an antibody to IL-13bc protein encoded by a nucleic acid which varies from the

nucleic acid sequence of SEQ ID NO:3, as a result of the degeneracy of the genetic code, or an antibody to IL-13bc variant.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The following is a quotation of the second paragraph of 35 U.S.C. 112:
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 50, 51, 52, 58, 60, 66, 68, 74, 76, 78, 82 and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claim 50, 52, 58, 60, 66, 68, 74, 76, 82 and 84 are indefinite because the claims recite ".....the antibody useful in treating or modulating.....", however, the metes and bounds of the claims can not be ascertained, because it is unclear how does the claimed antibody *modulate* the recited diseases, does it induce or reduce the expression or IL-13? "modulate" encompasses both up-regulation or down-regulation, therefore, it is unclear how said modulation should be accomplished. Appropriate correction is required.

5b. Claim 51 recites "A comprising the antibody according to claim 46....", it appears that "composition" is inadvertently left out form the claim. Appropriate correction is required.

Conclusion

6. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-

8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
14 August 2003

Gary L. Kunz
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